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USER MANUAL AND TECHNICAL DECRRIPTION

Air2Care

Air Mattress System

ALTERNATING PRESSURE PUMP WITH MATTRESS

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1. IMPORTANT SAFEGUARDS AND STATEMENTS

When using electrical products, especially when children are present, basic safety present, basic safety precautions should always be followed, including the following:

Warning

If any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Danger

To reduce the risk of electrocution:

- Always unplug this product immediately after use.
- Do not use while bathing.
- Do not place or store product where it can fall or be pulled into a tub or sink.
- Do not place in or drop into water or other liquids.
- Do not reach for a product that has fallen into water. Unplug immediately.

Warning

To reduce the risk of bums, electrocution, fire, or injury to persons:

- A product should never be left unattended when plugged in.
- Close supervision is necessary when this product is used by, on, or near children or invalids.
- Use this product only for its intended use as described in this manual.
- Do not use attachments not recommended by the manufacturer.
- Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to a service center for examination and repair.
- Keep the power supply cord away from heated surfaces.
- Never block the air openings of the product or place it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air openings free of lint, hair, and the like.
- Never drop or insert any object into any opening or hose.
- Do not use outdoors or operate where aerosol (spray) products are being used.
- Connect this product to a properly grounded outlet only.
- Do not play with the supply cord and air hose of the product to prevent strangulation.

Note

Indicates some tips or some information users should be aware of.

Caution

Indicate correct operating or maintenance procedure in order to prevent damage to or destruction of the equipment or other property.

2. INTRODUCTION

This manual should be used for the initial set up of the system and for reference purposes.

2.1 General

The Air2Care Air Mattress System provides alternating pressure for patients who suffer from pressure ulcers at medium and high risk. The system is consisted of the highest quality of material which makes it durable and reliable in ICU environment, nursing home, and home care.

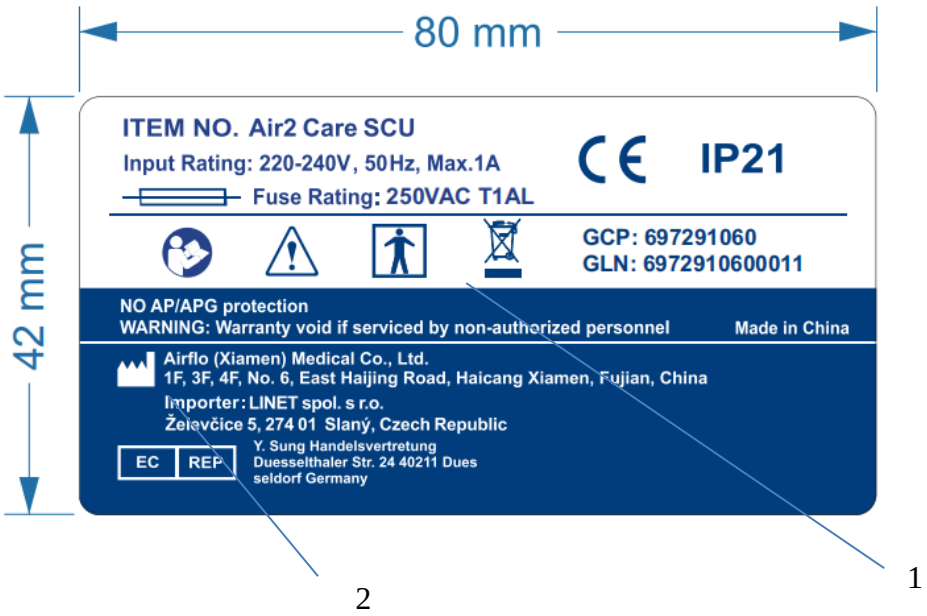
The system has been tested and certified for the following standard:

- EN ISO 13485
- EN 60601-1
- EN 60601-1-2
- EN 60601-1-6
- EN62304
- EN ISO 10993-1 (Cover)
- EN ISO 10993-5 (Cover)
- EN ISO 10993-10 (Cover)
- BS7175 (non-harmonized)(Cover)
- EN 597-1
- EN 597-2

2.2 Product Label and Technical Label

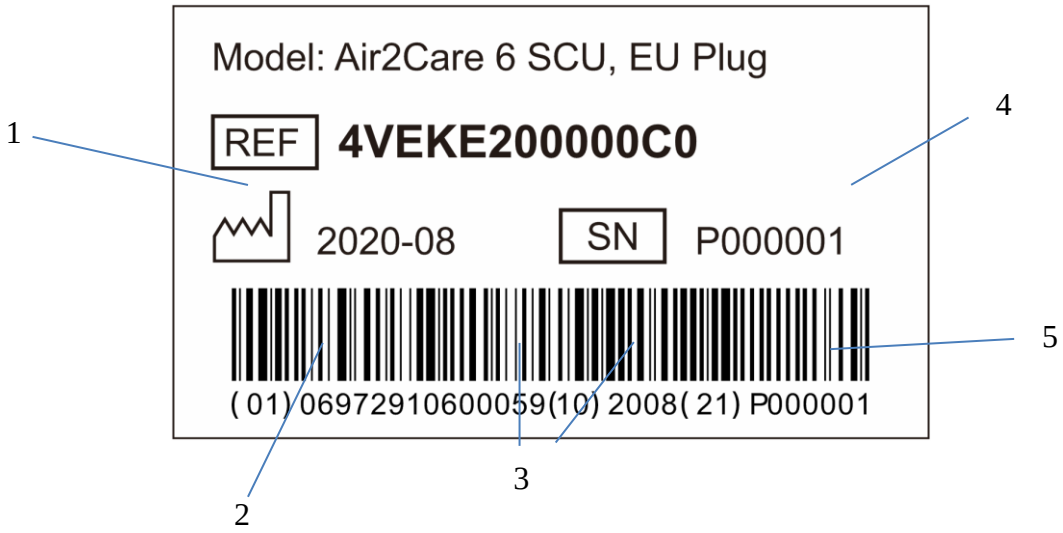
The legal label and UDI label are located on the back of the SCU (system control unit). The serial number, model number, and the input rating can be found on the label. This information is required if any issue occurs.

Figure 1. Legal Label



1	Address of Manufacturer
2	Symbols

Figure 2. UDI Label



1	Manufacturing Date (Year-Month)
2	DI (Device Identifier) / GTIN (Global Trade Item Number)
3	PI (Product Identifier)
4	Serial Number
5	1D Bar Code GS1-128 (Serial Number)

Figure 3. Wash Label (Air2Care - Mattress)

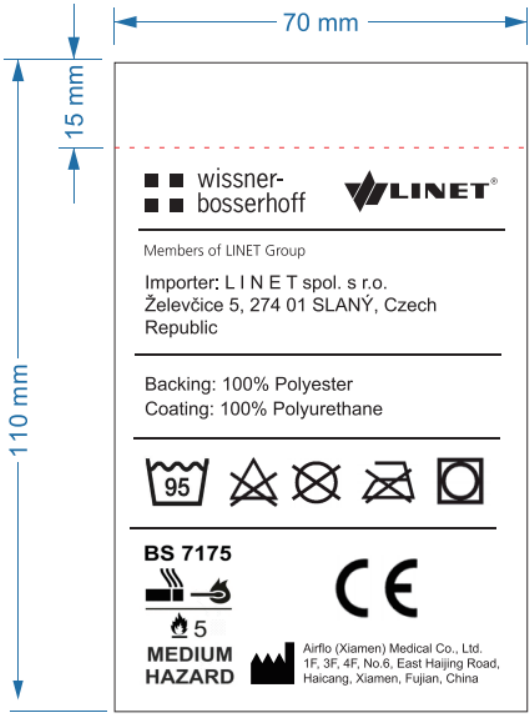
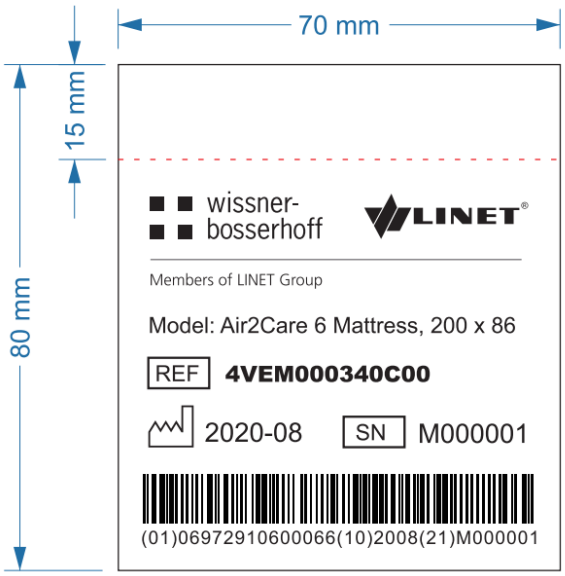


Figure 4. Serial Label with UDI (Air2Care - Mattress)



3. INTENDED USE

- To help and reduce the incidence of pressure ulcers while optimizing patient comfort.
- For home care, long-term care, and hospital care patients suffering from pressure ulcer.
- For pain management as prescribed by a physician.
- The PATIENT can be an intended OPERATOR.

Warning:

(1) No servicing and maintenance can be performed while the product is in use.
(2) All the functions can be operated by patient.
(3) No maintenance except for cleaning can be performed by patient.
(4) Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

4. CONTRAINDICATIONS

Patient conditions for which the application of pressure relieving therapy on an alternation system is contraindicated are as following:

(1) Cervical or skeletal traction.
(2) Unstable spinal cord injuries.
(3) The patient's wound cannot be in direct contact with the mattress.

5. PRODUCT DESCRIPTION

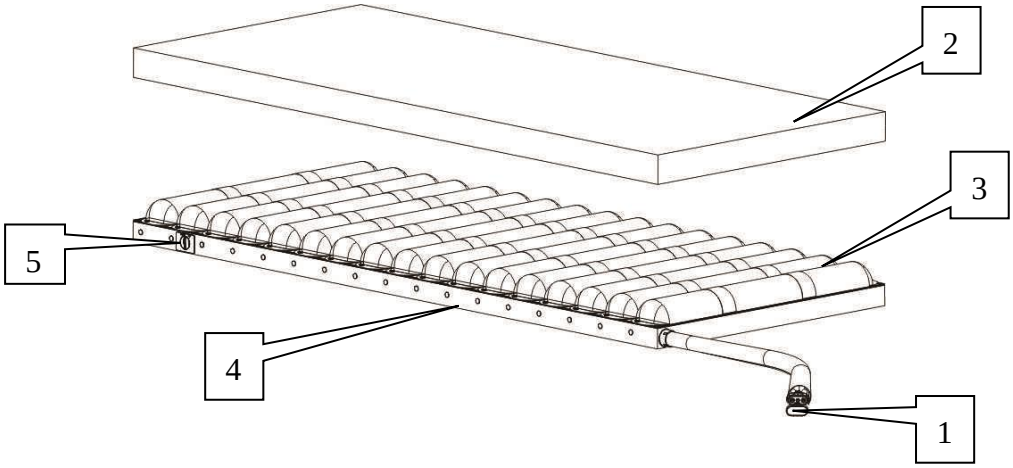
5.1 Mattress (Type BF applied part)

The Air2Care SCU comes with cell type mattress of different dimensions and constructions, provided optionally with the SCU.
Please refer to the specifications section for details.

Statement: The mattress has been evaluated by EN ISO10993-1 biocompatibility. Users should not experience allergic reaction after in contact the mattress. However, if you suspect that you may have had or are having an allergic reaction, please consult a physician immediately.

5.1.1 Air2Care 5 Overlay

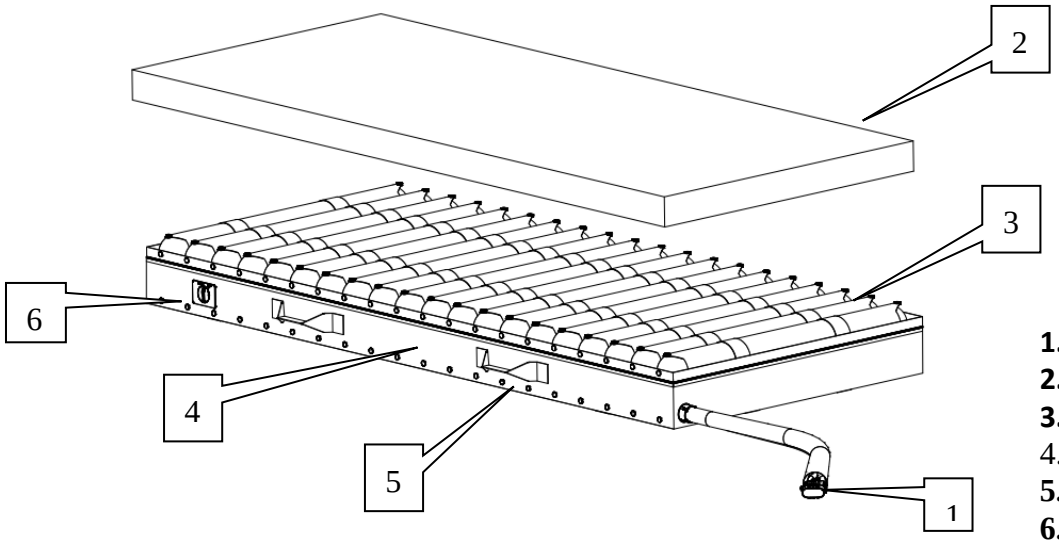
5-inch overlay system with single air deck. The 17 transverse air cells in the air layer alternate in pressure, with the exception of 3 static head cells. CPR locates at the head section in case rapid deflation is required. Loops are implemented at the base of the mattress for air cells fixation.



1. Quick Connector
2. Mattress Top Cover
3. Air Cell Set
4. Mattress Base Cover
5. CPR

5.1.2 Air2Care 6 Mattress Replacement

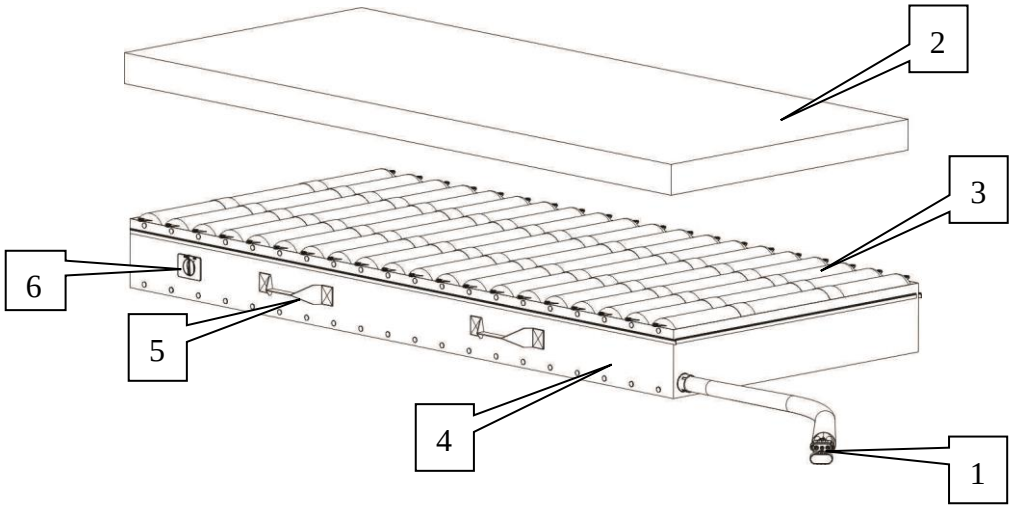
6-inch replacement system with cell-on-cell structure. The 20 or 21 transverse air cells in the air layer alternate in pressure, with the exception of 3 static head cells. CPR locates at the head section in case rapid deflation is required. Loops are implemented at the base of the mattress for air cells fixation.



1. Quick Connector
2. Mattress Top Cover
3. Air Cell Set
4. **Mattress Base Cover**
5. Handle
6. CPR

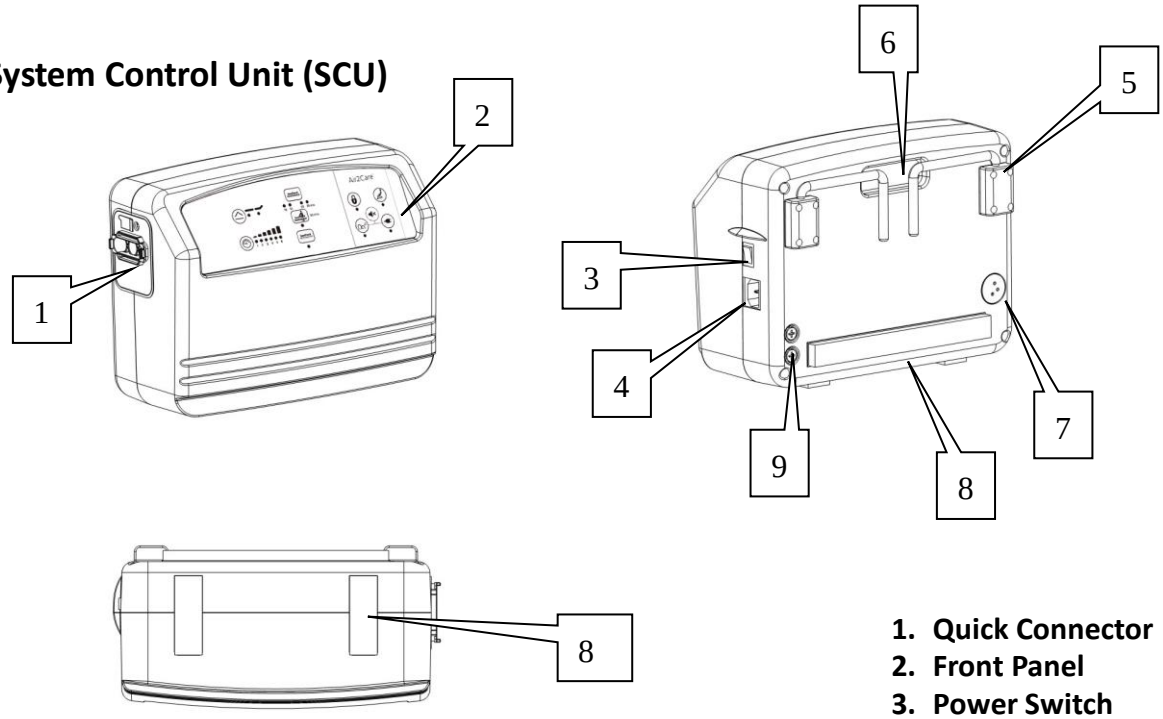
5.1.3 Air2Care 8 Mattress Replacement

8-inch replacement system with cell-on-cell. The 20 transverse air cells in the air layer alternate in pressure, with the exception of 3 static head cells. CPR locates at the head section in case rapid deflation is required. Loops are implemented at the base of the mattress for air cells fixation.



1. **Quick Connector**
2. **Mattress Top Cover**
3. **Air Cell Set**
4. **Mattress Base Cover**
5. **Handle**
6. **CPR**

5.2 System Control Unit (SCU)



1. **Quick Connector**
2. **Front Panel**
3. **Power Switch**
4. **Power Socket**
5. **Handle Groove**
6. **Integrated handle**
7. **Filter Cotton**
8. **Foam Damper**
9. **Fuse**

5.2.1 Power Source

Power cable is connected to the connector on the compressor back side. Then the power leads to the main switch. A main ON/OFF switch was implemented on the exterior of the SCU. Another power switch was implemented on front panel and are labeled as such. When the main switch is ON, the power leads to the lower PCB, which will direct the voltage to the compressor unit and to the transformer. Two 1A fuses were utilized. As the voltage enters from power supply, the transformer will transform the voltage to 10V AC and then regulated to 5V DC by rectifier. The primary part of transformer is equipped with thermal protection. The power board is also equipped with relay for compressor / synchronize motor / microswitch activation and deactivation. The relay is controlled by the IC of PCB, which uses 5V DC.

5.2.2 Control Board

The lower PCB is the main control unit of the SCU, and it is powered by 10V DC. Lower PCB is also connected to the upper PCB, which powers the front panel control. Control board provides the following function:

- Control of SCU functions – according to selected modes on the front panel
- Display information on the front panel.
- Pressure measurements – activate pressure sensors.
- Compressor control
- Synchronize motor and microswitch control
- Backrest switch

5.2.3 Pressure Measurement

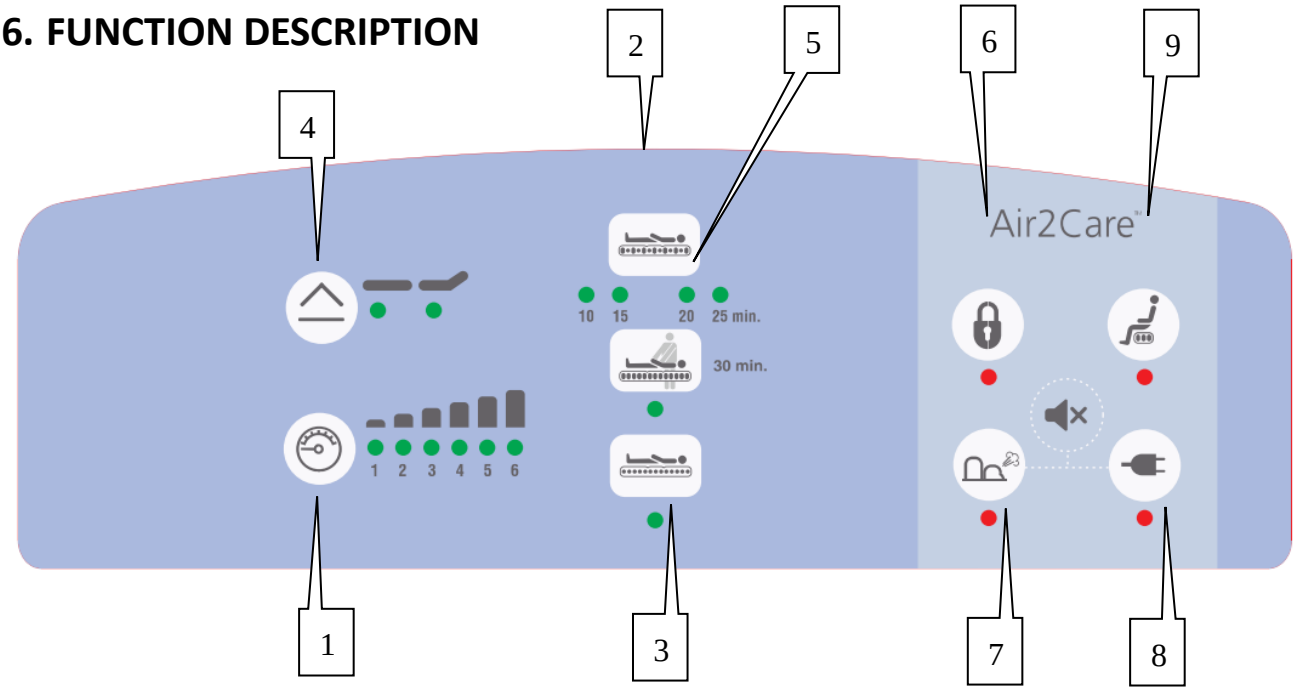
The pressure in mattress air cells is measured by pressure sensors that is controlled by the lower PCB. Pressure sensor is implemented on the lower PCB. A hose is connected from the lower PCB to the compressor to measure the pressure.

Air2Care 5 (Max. load: 140 kg)	Level	kg	mmHg	Maxfirm
	1	40	13	45mmHg
	2	60	20	
	3	80	25	
	4	100	30	
	5	120	35	
	6	140	40	

Air2Care 6 (Max. load: 160 kg)	Level	kg	mmHg	Maxfirm
	1	40	13	45mmHg
	2	60	20	
	3	80	25	
	4	100	30	
	5	130	35	
	6	160	40	

Air2Care 8 (Max. load: 180kg/250kg)	Level	86cm WIDE kg	> 86cm WIDE kg	mmHg	Maxfirm
	1	40	40	13	45mmHg
	2	70	80	20	
	3	100	120	25	
	4	130	160	30	
	5	160	200	35	
	6	180	250	40	

6. FUNCTION DESCRIPTION



6.1 Comfort Weight Setting

6.1.1 Manual Weight Setting

Adjust the air pressure levels by pressing the comfort weight setting button. The pressure increases one level by each pressing until the maximum pressure level is reached. The Green LED light will indicate the selection of the pressure level. When the pressure is at the maximum level, the pressure will go back to the first level after pressing the same button.

6.1.2 Auto Weight Calculating - Easy Smart Series

Press to enter into Auto Weight calculating mode. The Green LED lights will flash during the calculating and will stops at the optimum pressure level when the calculating is complete.

When the system is determining the patient weight the SCU is also calculating the optimum pressure level for that weight of patient. The process occurs every 5 hours or when the SCU detects.

Caution:

When a patient's condition has significantly changed, reassess the comfort weight setting level. The weight-pressure label in front of the SCU can be taken for reference when selecting the pressure level. A hand check is needed to determine if patient is bottoming out.

6.2 Alternate & Cycle Time Button

1:2 alternating pressure cell cycle with 10, 15, 20, 25 minutes cycle time intervals available for selection. The Green LED light will stop at the desired cycle time by pressing the Alternate & Cycle Time Button.

Caregivers may choose based on patient comfort and desired outcome to achieve periodic pressure relief.

6.3 Static Button

Press to set the air mattress in static therapy mode. The Green LED light will indicate the selection of the mode. Patient's body mass will be redistributed over greater surface area at a constant air pressure based on the comfort weight setting.

6.4 Seat Inflate Button 

When the seating sensor detects the mattress is raised up to a seating state, the SCU will automatically enter into seat inflate mode. The Green LED light will indicate the selection of the mode.
If the seating sensor is disconnected or out of order, press the seating button manually to enter into seating mode.

6.5 Max Firm Button 

Press to set the air mattress in quick inflation mode, which facilitates nursing and Caring. The Green LED light will indicate the selection of the mode.
Once the maximum pressure level is reached, the SCU will automatically revert back to the previously selected comfort level within 30 minutes.

6.6 Unlock Button 

Press to lock or unlock the panel. The Green LED light will indicate the state of panel being locked.
Auto: Should the panel remain untouched for 5 minutes, the panel lock feature will lock the panel. To unlock, press Unlock button for 2 seconds.
Manual: Press the Unlock button for 2 seconds to lock the panel, press again for 3 seconds to unlock the panel.

6.7 Leaking Alarm 

Should there be a bad connection of tubing or any air leakage from the mattress, the Red Leaking LED light will light up and the audible alarm will activate within 20 seconds. The Leaking Alarm button can be pressed to mute the audible alarm. Once the pressure returns to normal, the SCU will resume operation in the previously set mode automatically, and the Red Leaking LED light will go out.

6.8 Power Failure Alarm 

Should there be power failure outage, the Red Power Failure LED light will light up and the Power Failure alarm will activate immediately. Press the POWER button to deactivate the audible alarm. When power is back, the Red Power Failure LED light will go out and the SCU will automatically start working. Do not press power button again.

6.9 Cushion 

Press the button if in need of connecting the SCU with a seat cushion. The Green LED light will indicate the selection of the mode.

7. CLASSIFICATION

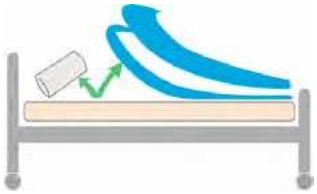
- Electrical safety class - Class II
- Type BF Applied Part (The mattress is applied part).
- IP21.
- Continuous operation.

Caution: The plug of supply cord is used as the isolation means from mains, do not to position the product to make it difficult to operate this disconnection device

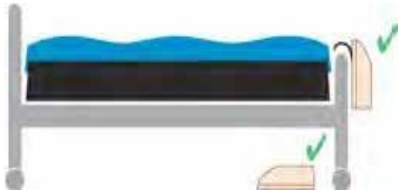
8. INSTALLATION

The following describes the procedures for setting up the system for the first time.

a) Remove all covers, sheets and mattress from the bed.



b) Place the mattress on top of bed frame, printed top cover facing upwards and air hoses towards the base of the bed. Secure the mattress firmly by fixing the straps to the bed frame. Ensure buckles are securely fastened and straps are pulled tight.



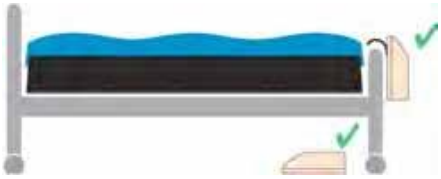
c） On a profiling bed, secure the side straps around the moveable sections of the bed base. **DO NOT SECURE TO THE SIDE RAILS - STRAPS WILL TEAR OFF.**

d) Confirm there are no sharp objects in the immediate area which may risk damage to the Mattress Replacement.

Important: Check that the attachment of the Mattress Replacement does not interfere with the movement or operation of the bed.

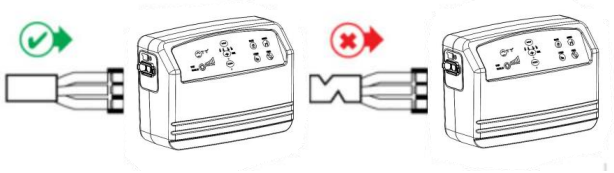
SCU Activation

a) Position the SCU by hanging hooks over foot board of the bed or place unit on the floor under the bed.

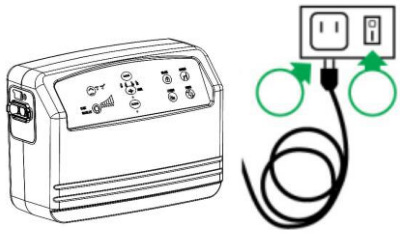


b) Attach the air hoses through the use of the quick connector to the SCU. Ensure air hoses do not kink between mattress, bed frame and the SCU.

b) Plug the power cord into an electrical outlet with grounded AC power.



NOTE: Before inserting the plug into the outlet, make sure the voltage is compatible. Also make sure this product is well grounded.



d) Switch the power button on. Allow up to 40 minutes for full inflation.

e) Once ready, the low pressure light will go out - lay the patient on the bed and select the appropriate comfort level.

Perform a “bottom out” test to ensure that patient is properly suspended. Slide your hand under the top cover along a deflated cell in the sacral (bottom) area. Secure sheets loosely enough to ensure they do not interfere with cell alternation.

9. OPERATING INSTRUCTIONS

NOTE: Always read the operating instructions before use.
This system is designed to provide maximum comfort to patients. Follow the information provided below to optimize the functionality of the system.

9.1 For products:

- DO NOT use another SCU with different specifications unless instructed to do so by your local dealer.
- DO NOT change any component by yourself. If there is need for replacement or repair, always contact your local dealer.

9.2 For patients:

- When the pressure has been adjusted to a desired level of firmness, the patient can then lie on the mattress.

9.3 General Operation

Step 1. Turn on the power, A beep sound will begin the operation.

Step 2. When the power is initially turned on, the SCU will automatically enter into “Static Mode” for a few minutes of inflation.

Note: If the mattress can’t be fully inflated within 90 minutes, the LEAKING alarm will be triggered, and its LED indicator will light up.

Step 3. Select from the touch panel to adjust the cycle time and the pressure level to the patients’ specific requirements. Users can adjust the pressure level of the air mattress to a desired firmness by themselves or according to the suggestion from a health care professional.

Hand check: Check if the pressure is properly adjusted by sliding one hand between the air mattress and bed frame to feel the patient’s buttock. Users should be able to feel the space in between, and the acceptable range is approximately 25 to 40 mm (1” to 1-1/2”).

Step 4. Press Alternate, Static or Seat Inflate to choose a desired therapeutic mode according to patient’s actual demand or the suggestion from a health care professional.

Note: A firm surface allows easier patient transfer or reposition. Make use of the static mode function for this feature. Press the static mode button from the touch panel.

Note: To sit a patient up in bed, press the Seat Button to increase the pressure to have better support on sacrum area.

Step 5. Max Firm can be selected from the panel to achieve full mattress inflation for situations like patient ingress/egress or normal nursing procedure for better support.

Step 6. If there’s a special need of changing the air mattress to a cushion. Press the Cushion button first, and replace the mattress with a seat cushion.

9.4 CPR

When there is an emergency requirement to perform CPR on the patient, turn the CPR knob from "Close" to "CPR" to release the air quickly from the mattress.

9.5 Disconnect Device

To fully disengage the power to the unit, please disconnect the power cord from the AC inlet.

10. ENVIRONMENT REQUIREMENTS

10.1 Operating Conditions

- Ambient Temperature: 5℃~ 40℃
- Relative Humidity: 15%~90%, non-condensing
- Atmospheric pressure: 700hPa to 1060hPa

10.2 Storage and shipping conditions

- Ambient temperature: -25℃~70℃
- Relative Humidity: 10%~90%, non-condensing
- Atmospheric pressure: 700hPa to 1060hPa

10.3 Handling and Storage

- Lay the mattress out flat and upside down.
- Roll from the foot end towards the head end; the foot-end strap can then be stretched around the rolled mattress to prevent unrolling.
- Do not fold, crease or stack the mattress.

11. CLEANING GUIDELINES

Follow the below procedure to clean and decontaminate the system. It is important to follow these steps before using the system again. Cleaning task is required at least once a week to maintain personal hygiene.

11.1 System Control Unit (SCU)

- DO NOT immerse or soak the SCU in any water or fluids.
- Check for external damage and move the SCU to the cleaning area.
- Place the SCU on a work surface and spray or wipe the outside of the case with quaternary ammonium solution.
- DO NOT spray any cleaning solution directly on the surface of the SCU.
- DO NOT use a Hypo carbonate or Phenolic based cleaning solution as this may cause damage to the case. Allow the solution to incubate for 10 minutes or accordingly as stated by the cleaning product instructions.
- Wipe case with a clean cloth. Make sure all areas are clean (top and bottom, both sides).
- Spray cloth with cleaning solution and clean faceplate. DO NOT allow excess cleaning solution on faceplate or control panel(If solution gets inside, damage will occur). Allow surface to thoroughly dry after cleaning.
- After the SCU is thoroughly cleaned and dried, proceed to plug in the SCU and test to see if it runs normally.
- Unplug the SCU and store with proper identification tag.
- Avoid long exposure to sunlight.

11.2 Mattress

- Brush off or wipe down all surfaces of the cover sheet with soap and water before wetting with any liquid disinfectant.
- Any obvious blood spots should be wet thoroughly with 1:9 Hypochlorite solution (1 part bleach to 9 parts water) and allow drying for at least 10 minutes. Then blot with a clean, damp cloth.
- Unzip the top cover from the mattress.
- Brush or wipe down all surfaces with soap and water before applying any liquid.
- Covers are immersed and soaked in disinfectant for the required incubation time.
- After pre-soaking, the cover is rinsed through a regular cycle in a washer with no soap then laundered with mild detergent (wash temperature 93°F/34°C, rinse temperature 78°F/26°C or on the coldest setting).
- Covers are aerated until they are fully dry.
- The air cells are unsnapped from one side and are sprayed on all sides with a disinfectant. Let it sit for the required incubation time and wipe down with a clean cloth. (Make sure to disconnect all the air cells, one by one, and spray the disinfectant on all sides, including all the connecting tubes and hoses. Let it sit for least 10 minutes.)
- If there is a base after you remove all the air cells, the base has to be sprayed down with the disinfectant, inside and outside. Let it sit for the required incubation time and wipe down with a cloth.
- Repeat the process with the tubing set: spray, incubate, and then wipe clean.
- The carrying bag should be turned inside out and completely wiped down using the disinfectant solution. Allow it to thoroughly air dry. Once the inside is dry, turn it back: wipe down the outside of the bag with disinfectant.
- Dry the mattress on a flat surface area after cleaning, away from exposure to the sun.
- Avoid long exposure to sunlight.

Statement: If used by different patients, before use to carry out cleaning and disinfection.

12. MAINTENANCE

12.1 General

- Check the power cord and plug to see if there are abrasions or excessive wear.
- Check the mattress cover for signs of wear or damage. Ensure the mattress cover and tubes are connected together correctly.
- Plug in the SCU and check the airflow from the hose connection port. The airflow should alternate between ports every half-cycle time.
- Check the air hoses to see if there are any kinks or breaks. For replacement, please contact your local agent or dealer.
- Make sure the mattress tube is well connected.
- Check the SCU and make sure both power indicators are off when the switch is turned off.

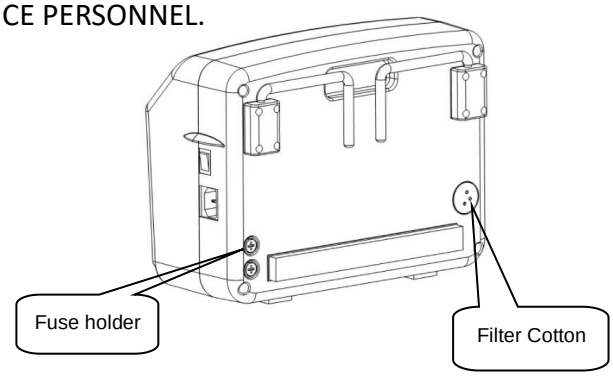
12.2 Low pressure

Examine if there is any air leakage between the SCU and the mattress connections or from the air mattress tubes:

- Check connectors between the air mattress and the SCU. If there is any disconnection, please reconnect it.
- Check the air-connecting tubes. Ensure each single cell is not broken.
- Set the pressure at Max firm. Keep the tubes fully inflated and inspect for air leakage.
- Check if there is any air leakage from cells. Ensure no leakage occurs. If any leakage occurs, please contact your local agent or dealer.

Statement: Power supply cord and Fuse can be replaced by SERVICE PERSONNEL.

1) Turn off the power, unplugged the power supply cord.
2) Unscrew the sleeve from fuse holder on the bottom enclosure of the SCU, replace the fuse inside of sleeve with same specification of fuse, screw the sleeve back to fuse holder.
3) Fuse rating: T1AL 250V 5A 250V



Warning:

No modification of this equipment is allowed.

Never open the equipment. For safety reasons, only qualified service personnel should open the equipment.

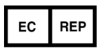
MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

Statement: LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION should contact the MANUFACTURER or the MANUFACTURER'S representative for assistance in setting up, using or maintaining the product and to report unexpected operation or events.

13. TROUBLE SHOOT

Problems		Reasons	Maintenance
Mattress fail to inflate or do not inflate completely.	SCU issue	1.SCU does not work.	1. After powered on, check if visible LED light turns on. If not, please check the below issues: 1.1 Check if power cord is plugged into appropriate voltage AC outlet. 1.2 Check if fuse is loose or burned out, make sure, it's connected well or replace with new one. 1.3 Open the SCU and see if wires inside are connected well, make sure they are not loose. 1.4 Change lower PCB.
		2.Air pressure from SCU is too low.	1. Check if air pressure and air flow (100mmHg, 8.0L) are high enough from the compressor, if not then replace with new compressor. 2. Check if there is air leakage from the exchanger, if yes then replace with new exchanger. 3. Check if silicone tube inside the SCU is connected well.
	Mattress issue	1. Quick connector on mattress does not connect well with SCU. 2. Air tube connected to T/L connector and air valve are loose, CPR connector is not capped. 3. One way valve is broken. 4. Air cell is leaking.	1. Make sure quick connector on mattress is connected well with SCU. 2. Make sure T/L connector and air valve is connected well, CPR connector is capped well. 3. Change one way valve. 4. Change air cell.
Mattress has pillow function, but air cell fails to inflate.		1. One way valve is assembled reversely.	1. Assemble the one way valve in correct direction.
SCU is working but synchronous motor does not work; thus, mattress does not alternate.		1. Synchronous motor is out of order. 2. Wires inside synchronous motor not connect well. 3. Lower PCB is out of order.	1. Change synchronous motor 2. Make sure wires are connected well. 3. Change the lower PCB.
SCU and motor keep working, but cycle time is incorrect.		1. Micro switch on the exchanger is out of order. 2. Lower PCB is out of order.	1. Change the micro switch. 2. Change the lower PCB.
When powered on, compressor stop after working some time; but the exchanger keep rotary.		1. Pressure detector is out of order.	1. Change the lower PCB.
Mattress pressure is low but alarm is not activated.		1. Pressure detector is out of order.	1. Change the lower PCB.
Push button on panel is not operated well, and LED indicator does not light up.		1. Push button is not operated well. 2. LED is out of order.	1.Change the upper PCB.
Mattress pressure is too high or too low.		1. Pressure sensor is out of order.	1. Change the lower PCB.
Power failure alarm can't be activated after power failure.		1. Battery is out of order.	1. Change the lower PCB.

14. SYMBOLS

Symbol	Meaning
	Power ON.
	Power OFF.
	Alternating current.
	Manufacture.
	Authorized representative in the European Community.
	Date of manufacture.
	Series number.
	Class II Medical electric equipment.
	Type BF applied part.
	Refer to instruction manual/ booklet.
IP21	Degree of protection against harmful ingress of water and particulate matter.
	Caution.
CE 0197	CE certification.
	General warning sign.
	Do Not Bleach
	Do Not Iron
	Tumble Dry, Normal, Low Heat
	Dry clean, Any Solvent Except Trichloroethylene
	Machine wash, regular / normal, 95 degrees C (203 degrees F)

	Disposal of Electrical & Electronic Equipment (WEEE): This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.

15. TECHNICAL SPECIFICATIONS

System Control Unit (SCU)	
Item:	Air2Care SCU
Input rating:	220-240V, 50Hz, Max.1A
Air output:	8 liter/min
Pressure range:	13 mm Hg – 40 mmHg
Cycle time:	10/15/20/25 min
Case Material:	Flame Retardant ABS
Mode:	Max firm mode, Alternate/Static/Seat inflate mode
warning:	Low pressure, Power failure, Seating Sensor Malfunction
Accessory:	Power supply cord, VDE Mark, 3*0.75mm2
PEMS Version	A2C-568-E01

Accessory: Mattress			
Item:	Air2Care 5	Air2Care 6	Air2Care 8
Size:	200x86x12.5cm	200x86x15cm 200x90x15cm 210x86x15cm 210x90x15cm	200x86x20cm 200x100x20cm
Air Cell:	17 x TPU cells Single cell Structure 3 head cell static 6-11 cells ventilated Self-closing T-valve	20/21 x TPU cells Cell on cell Structure 3 head cell static 6-11 cells ventilated Self-closing T-valve	20 x TPU cells Cell on cell Structure 3 head cell static 6-11 cells ventilated Self-closing T-valve
Max. load:	140kg	160kg	86cm wide: 180kg ⩾86cm wide: 250kg
Top cover:	Bi-elastic PU Coating Breathable, Slip-retardant, Waterproof, Washable to 95°C Flame retardancy BS 7175, Biocompatibility, Cytotoxicity, Antibacterial		
Base Cover:	Nylon / PVC (840D/60T) With 4 fixing straps, and 2		
Function:	CPR valve for emergency procedures		

	Self-closing bladders to freely position the patient easily Low air loss Pillow function Quick connector for Transportation

16. EMC GUIDANCE

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

Caution:

1) Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
2) This unit has been thoroughly tested and inspected to assure proper performance and operation.
3) This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d=1.2\times P\ 1^{/2}$	**80 MHz to 800 MHz** $d=1.2\times P^{1/2}$	**800 MHz to 2,5 GHz** $d=2.3\times P^{1/2}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	±2kV for power supply lines ±1kV for interconnecting cable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line	Mains power quality should be that of a typical commercial or hospital environment.
interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U T (>95% dip in U T .) for 0.5 cycle 40 % U T (60% dip in U T) for 5 cycles 70% U T (30% dip in U T) for 25 cycles <5% U T (>95 % dip in U T) for 5 sec	<5 % U T (>95% dip in U T .) for 0.5 cycle 40 % U T (60% dip in U T) for 5 cycles 70% U T (30% dip in U T) for 25 cycles <5% U T (>95 % dip in U T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the model Scorpio be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE *U*T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 10 V/m 80 MHz to 2.7 GHz **385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)**	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 10 V/m 80 MHz to 2.7GHz **385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)**	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[3,5/V_1]\times P^{1/2}$ $d=1.2\times P^{1/2}$ *80 MHz to 800 MHz* $d=2.3\times P^{1/2}$ *800 MHz to 2.5 GHz* where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

17. EXPECTED SERVICE LIFE: 2 years.

Statement: Follow the national requirement to dispose unit.